K103465

JAN 3 1 2011

5. 510(k) Summary

Date Prepared:

November 23, 2010

Submitter's Information:

FUJIFILM Medical Systems USA, Inc.
419 West Avenue
Stamford, Connecticut 06902

Telephone: (203) 602-3774
Facsimile: (203) 363-3813
Contact: Debra A. Peacock

Device Trade Name:

Synapse 3D Cardiac Tools

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name

Picture Archiving Communication System (PACS)

Panel:

Radiology

Product Code:

90-LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Devices:

- Voxar 3D Enterprise with CardiaMetrix, K061326
- ZIO Soft MR Cardiac Function Analysis, K091262
- GE CardIQ Fusion, K061370

Description of the Device

Synapse 3D Cardiac Tools is with Fujifilm's Synapse 3D Basic Tools (K101662, cleared by CDRH on July 26, 2010) and can be integrated with our cleared Fujifilm's Synapse Workstation, version 3.1.0 and above as a part of a Synapse system. Synapse 3D Cardiac Tools also can be integrated with Fujifilm's Synapse Cardiovascular for cardiology purposes.

Synapse 3D Cardiac Tools offers physicians the following clinical applications in addition to the features available from our cleared Synapse 3D Basic Tools (K101662) to analyze the image data retrieved from various connected devices.

Functional cardiac analysis (CT)

Functional cardiac analysis (CT) is an application for cardiac function evaluation which obtains the boundary between left ventricle and cardiac wall from CT left ventriculography images retrieved from multiple time phases and calculates ejection fraction, end-diastolic volume, end-systolic volume, stroke volume, etc.

Functional cardiac analysis (MR)

Functional cardiac analysis (MR) is an application for cardiac function evaluation which obtains the boundary between left ventricle and cardiac wall from non-contrasted MR images retrieved from multiple time phases and calculates ejection fraction, end-diastolic volume, end-systolic volume, output volume per beat, etc.

Coronary artery analysis (CT)

Coronary artery analysis is an application using CT coronary arteriography images to extract the path of the target blood vessels and to perform coronary artery evaluation.

Calcium Scoring

The calcium scoring is an application which uses non-contrasted CT images to display the calcification area in the coronary artery with color separation and calculates the calcification quantitative values using the Agatston score method.

Cardiac Fusion

Cardiac fusion is an application to create an image having the mutual characteristics of source images of heart. Source images could be original image of CT, MR or NM and the functional image derived from the original image.

Indication for Use

Synapse 3D Cardiac Tools is medical imaging software used with Synapse 3D Basic Tools that is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Cardiac Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to the tools with Synapse 3D Basic Tools, Synapse 3D Cardiac Tools provides the tools for specific clinical applications which provide targeted workflows, custom UI, targeted measurements and reporting functions including:

- Functional cardiac analysis for CT left ventriculography images: which is intended to evaluate the functional characteristics of heart
- Functional cardiac analysis for non contrasted MR heart images: which is intended to evaluate the functional characteristics of heart
- Coronary artery analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries
- Calcium scoring for non contrasted CT heart images: which is intended for non – invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms
- Cardiac Fusion: which is intended to analyze cardiac anatomy and pathology with a fused image of functional data (e.g. NM image, Bulls eye) and anatomical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Debbie Peacock
Sr. Regulatory Affairs Specialist
FUJIFILM Medical Systems USA, Inc.
419 West Avenue
STAMFORD, CT 06092

JAN 31 2011

Re: K103465
Trade/Device Name: Synapse 3D Cardiac Tools
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 23, 2010
Received: November 24, 2010

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103465

Device Name: Synapse 3D Cardiac Tools

Indications for Use:

Synapse 3D Cardiac Tools is medical imaging software used with Synapse 3D Basic Tools that is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Cardiac Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to the tools with Synapse 3D Basic Tools, Synapse 3D Cardiac Tools provides the tools for specific clinical applications which provide targeted workflows, custom UI, targeted measurements and reporting functions including:

- Functional cardiac analysis for CT left ventriculography images: which is intended to evaluate the functional characteristics of heart
- Functional cardiac analysis for non contrasted MR heart images: which is intended to evaluate the functional characteristics of heart
- Coronary artery analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries
- Calcium scoring for non contrasted CT heart images: which is intended for non – invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms
- Cardiac Fusion: which is intended to analyze cardiac anatomy and pathology with a fused image of functional data (e.g. NM image, Bulls eye) and anatomical data.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103465